UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/482,585	01/13/00	HANGAUER	D 19226/931 (R

HM12/0328

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EXAMINER	
PRASTHOFER, T	
ART UNIT	**PAPER NUMBER**
1627	9

DATE MAILED: 03/28/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/482,585	HANGAUER ET AL.	
	Examiner	Art Unit	
	Thomas W Prasthofer	1627	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 March 2001 and 16 March 2001* .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-69* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claims *1-69* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
18) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other: .

Detailed Action

Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 44 and 45, drawn to a non-peptide protein tyrosine kinase inhibitor of the formula shown in claims 44, classified in class 548, subclass 478.

II. Claims 46-48, drawn to a non-peptide protein tyrosine kinase inhibitor of the formula shown in claims 46, classified in class 564, subclass 123.

III. Claim 49, drawn to a non-peptide protein tyrosine kinase inhibitor of the formula shown in claims 49, classified in class 548, subclass 478.

IV. Claims 24-43 (in part), and 50-69 (in part), drawn to methods of inhibiting a protein kinase and treating a condition, responsive to a protein kinase inhibitor, classified in class 514, subclass variable depending on the inhibitor's structure.

V. Claims 1-20 (in part) and 22, drawn to a method for identifying inhibitors of protein kinase, classified in class 435, subclass 7.1.

VI. Claim 21 (in part) drawn to a method for identifying improved protein kinase inhibitors, classified in class 435, subclass 7.1.

VII. Claim 23 (in part), drawn to a method for testing compounds for an ability to inhibit protein kinase activity, classified in class 435, subclass 7.1.

The inventions are distinct, each from the other because:

2. Inventions I-III are different and patentably distinct compositions because they have different structures, and physical, chemical, and pharmacological properties.

3. Inventions IV-VII are different and patentably distinct methods because they use different compositions, include different method steps, and/or produce different results. For example, Invention IV is a method of inhibiting a protein kinase and treating a condition,

Invention V is a method for identifying protein kinase inhibitors, Invention VI is a method for identifying improved protein kinase inhibitors, and Invention VII is a method for testing compounds for an ability to inhibit protein kinase activity. The products of Invention V are used as starting materials for the method of Invention VI and the two inventions have different method steps. The method steps of Invention VII are different from the method steps of Invention V and produces different results.

4. Invention IV and Inventions I-III are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the methods of Inventions V and VI can be used to identify at least three materially different products, the compositions of Inventions I-III and the compositions of Inventions I-III can be produced by the two different methods of Inventions V and VI.

5. Inventions I-III and Inventions IV and VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the three materially different compositions of Inventions I-III can be used for the same method of Invention VII. Each of the compositions of Inventions I-III can be used in the two materially different processes of Inventions IV and VII.

6. The Examiner notes that the claims included in Inventions IV-VII read on diverse groups of core structures with different chemical, physical, pharmacological, and pharmacokinetic properties, and different means of chemical synthesis. As a consequence, there is no basis upon which to conduct a proper search of the prior art with respect to the chemical structures that are encompassed by the claims of Inventions IV-VII. The search of all claimed structures would therefore be burdensome.

7. If Applicant elects any of Inventions IV-VII, restriction to ONE of the following inventions is required:

A). wherein the second group consists of indole, class 546, subclass 85,

B). wherein the second group consists of naphthalene, class and subclass variable, depending upon the structure of the molecule,

C). wherein the second group consists of biphenyl, class and subclass variable, depending upon the structure of the molecule,

D). wherein the second group consists of isoquinoline, class 546, subclass 134,

E). wherein the second group consists of benzofuran, class 549, subclass 20+,

F). wherein the second group consists of benzothiophene, class 549, subclass 2+,

G). wherein the protein kinase inhibitor has the formula shown in claims 37 and 64, classified in class 514, subclasses 419,

H). wherein the protein kinase inhibitor has the formula shown in claims 38 and 65, classified in class 514, subclass 622,

OR

I). wherein the protein kinase inhbitor has the formula shown in claims 40 and 66, classified in class 514, subclass 419.

8. Because these inventions are distinct for the reasons given above and

a. have acquired a separate status in the art as shown by their different classification;
b. have different and separately burdensome manual and/or computer, structure, name, and bibliographical searches; and
c. have divergent subject matter, restriction for examination purposes as indicated is proper.

Election of Species

9. This application contains claims directed to different and patentably distinct species of invention. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

10. If Applicant elects any of Inventions IV-VII, Applicant is required to elect an ultimate species for each of the following:

A. peptide scaffold,

B. functional group (claim 3),

AND

C. an exact structure of a protein kinase inhibitor (both modified and unmodified for Invention VI).

11. The species are distinct, each from the other, because the molecules have different chemical, physical, biochemical, pharmacological, and/or pharmacokinetic properties. Therefor, different issues of enablement and patentability apply to each species and each species represents patentably distinct subject matter.

12. Applicant is required under U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally to be allowable.

13. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the

examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

14. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

15. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently filed petition under 37 CFR 1.48(b) and by the fee required under CFR 1.17(h).

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Thomas W. Prasthofer** whose telephone number is **(703) 308-4548**. The examiner can normally be reached on Monday-Friday, 8:00-4:30.

17. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jyothsna Venkat can be reached on (703) 308-2439. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-2742.

18. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

BENNETT CELSA
PRIMARY EXAMINER

Thomas Prasthofer, Ph.D.

March 26, 2001